K103796

AUG - 3 2011

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510(k)

PREMARKET NOTIFICATION

SUMMARY

1. **Submitter Details:** TeleMedCare Pty Ltd
2. **Contact Person:** Steven M Moody, QA/RA Manager
3. **Date of Preparation:** December 15, 2010
4. **Name of Device:**
   - 4.1. Trade Name: TeleMedCare Health Monitor
   - 4.2. Common Name: Patient Monitor – multiparameter
   - 4.3. Classification Name: Transmitters and Receivers, Physiological Signal Radiofrequency (21 CFR 870.2910, Product Code DRG)
5. **Predicate Device(s)**
   - 5.1. Intel Health Guide PHS6000, Remote Patient Monitoring System K080798
   - 5.2. Philips Medical Systems M3810A TeleMonitoring System K023749
   - 5.3. Bosch Health Buddy K063612
   - 5.4. Tunstall Mytelemedic Plus K090886
   - 5.5. Carematix Wellness System K073038 & K100508

6. Device Description

The TeleMedCare Health Monitor is designed to be used in the home or community setting to enable remote care management of patients with chronic illness.

The TeleMedCare Health Monitor is an ergonomic design table top device with a touch screen and associated measurement components that may be integral or connected to it wirelessly or by cable. After measurements are recorded, the data is viewed and stored on the device then automatically transmitted via telephone modem or local area network (LAN) to a secure remote server. This data is then able to be viewed remotely over the web by the user's health care professional to assist them with chronic care management. Access to information stored and processed by the device is by means of password protection, encryption and use of collocated secure servers.

The device also provides a means of messaging and video teleconferencing between the patient and carer to discuss their health and treatment. Questionnaires may also be configured by the carer to gauge other aspects of a patients well being.

TeleMedCare software, captures, stores and transmits health data and access controlled carer's may set upper and lower limits to allow notification to them when these limits are exceeded to review health care management. The device however does not offer critical care or emergency support and requires professional medical interpretation for treatment of prescribed users.

The System has functionality and devices to record, store and transmit data for body blood pressure, glucose and oximetry, heart rate (ECG), lung function (Spirometry), body temperature and weight.

Power to the device is supplied by a medical grade power supply delivering 12 volts D.C to the system via a cable plugged into the back of the unit along with connection to tethered external measurement modules and the internet. The TeleMedCare Health Monitor has been tested and complies with international standards for electrical and electrocardiograph safety, electromagnetic compatibility and telecommunication standards.

7. Intended Use / Indication for Use

7.1. Intended Use

The TMC Health Monitor is intended to facilitate monitoring and transmission to a remote server of certain physiological parameters relevant to the remote management of health status and chronic disease conditions.

7.2. Indications for Use

The TMC Health Monitor is a system that provides:

- Monitoring and display of vital signs/health parameters.
- Management and scheduling of clinical measurements and questionnaires.
- A web connection to patient health information.
- Reporting to clinicians and allied health workers.

The device has been designed to provide the user with information to assist with an appropriate treatment program or further investigation.

8. Technological Charactersistics & Comparison

The TeleMedCare Health Monitor is substantially equivalent to the predicate devices indicated with respect to; the skill and capability required of intended users; the power source and type of hardware used; physical form and materials used in manufacture; the methodology of taking, recording, storing, displaying and transmitting health data via the internet to a secure server; the software technology used to process and protect the data including graphing, setting limits, providing messaging, questionnaires and the provision of tele/video conferencing that enhance remote care monitoring.

9. Safety & Efficacy

The TeleMedCare Health Monitor has undergone extensive internal bench testing, independent clinical trials and product evaluations by various health institutions and government and non-government organizations since it the first version of it was introduced in Australia in 2001. Since then hundreds of thousands of measurements have reliably been accumulated and reported to professional health providers without a single device recall. The device is currently CE marked and cleared for use in Australia, New Zealand and Europe.

The test criteria for the device has been established by reference and compliance with FDA recognized standards and the outcome of risk assessments for the initial and subsequent significant changes to the device in accordance with EN ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices.

A comparative analysis has established that the TeleMedCare Health Monitor in addition to being substantially equivalent to the identified predicate devices raise no new questions concerning the safety and efficacy of the device.

10. Conclusion

The TeleMedCare Health Monitor is substantially equivalent to the predicated devices identified with respect to;

- Intended and indication for use
- Energy used and delivered
- Type of information collected, stored, displayed and transmitted
- Hardware, software and communication technology used.
- Electrical safety, electromagnetic compatibility and telecommunication test standards compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TeleMedCare Pty Ltd
c/o Mr. Steven M. Moody
QA/RA Manager
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Rosebery
NSW 2018 Australia

AUG - 3 2011

Re: K103796
Trade/Device Name: TeleMedCare Health Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Signal Physiological Transmitters and Receivers
Regulatory Class: Class II (two)
Product Codes: DRG
Dated: July 21, 2011
Received: August 1, 2011

Dear Mr. Moody:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

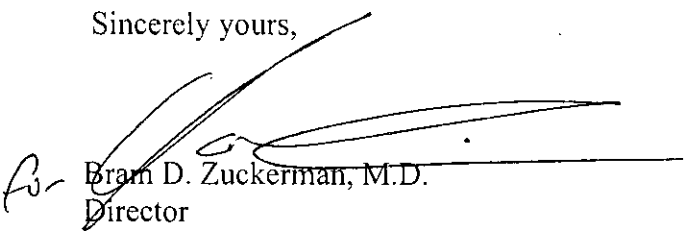
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement (page 1 of 1)

510(k) Number: K103796

Device Name: TeleMedCare Health Monitor

4.1 Intended Use :

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4.2 Indications for Use :

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Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Page 1 of 1

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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